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Unchalee Kositprapa

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EXAMINER

SASAN, ARADHANA

ART UNIT

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1615

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DELIVERY MODE

03/13/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/664,803	Applicant(s) KOSITPRAPA ET AL.	
	Examiner ARADHANA SASAN	Art Unit 1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 December 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 35-46 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 35-46 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>9/25/08</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of Application

1. The remarks, amendments, and Request for Continued Examination filed on 12/29/08 are acknowledged.
2. Claims 1-34 were cancelled.
3. New claims 35-46 were added and are included in the prosecution.

Continued Examination under 37 CFR 1.114

4. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 12/29/08 has been entered.

Information Disclosure Statement

5. The information disclosure statement (IDS) submitted on 09/25/08 is acknowledged. The submission is in compliance with the provisions of 37 CFR 1.97 and 1.98. Accordingly, the examiner is considering the information disclosure statement. See attached copy of PTO-1449.

Response to Arguments

Rejection of claims 1-4, 7-14, 17-20 and 31-34 under 35 USC § 103(a)

6. In light of Applicants' cancellation of claims 1-34, the rejection of claims 1-4, 7-14, 17-20 and 31-34 under 35 USC § 103(a) as being unpatentable over Cutie et al.

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(WO 01/82875) in view of Lewis (WO 01/35940) and further in view of Vergez et al. (US 2006/0204578) is rendered moot.

7. However, Applicants' arguments with respect to the newly added claims 35-46 have been fully considered but are not found persuasive.

Applicants argue that none of the references of record either alone or combined disclose or suggest to a skilled artisan a once a day metformin/pioglitazone product that employs a semipermeable membrane to control the release of the metformin and an immediate release pioglitazone coating that rapidly releases the pioglitazone with the aid of a primary seal coating between the semipermeable membrane and pioglitazone layer.

This is not persuasive because the controlled release of metformin is obvious over the metformin core taught by Cutie (Page 1, lines 6-7 and Page 10, claim 8) and Lewis (Page 1, lines 30-35). Since the metformin is in the core and the core can be coated with controlled release polymers, one of ordinary skill in the art would find that the controlled release of metformin from the dosage form is implicit.

The limitation of the immediate release of pioglitazone is obvious over the layer of pioglitazone hydrochloride on the core of metformin as taught by Cutie (Page 10, claim 8), in view of the thiazolidinedione that is formulated as a thin layer upon the surface of the metformin hydrochloride core as taught by Lewis (Page 1, lines 30-35). Since the pioglitazone is on the outer layer of the dosage form and there are no controlled release polymers or delayed release polymers required in the outer pioglitazone layer, one of ordinary skill in the art would find the immediate release of the pioglitazone from the dosage form implicit. Moreover, Lewis teaches immediate release

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of the thiazolidinedione. Due to the presence of the inert barrier separating the thiazolidinedione one of ordinary skill in the art would find it obvious that the metformin would only be released once the inert barrier was degraded, i.e., a controlled release of metformin from the inner portion of the dosage form would be obvious.

The semipermeable membrane would have been obvious over the semipermeable membrane taught by Vergez (Page 10, [0109]). One of ordinary skill in the art would combine the semipermeable membrane of Vergez with the dosage forms of Cutie and Lewis because the semipermeable membrane allows the controlled release of the metformin from the core of the dosage form.

Applicants argue that dependent claim 39 is patentable over the references of record because none of the references of record either alone or combined disclose or suggest to a skilled artisan a once a day metformin/pioglitazone product that controls the release of the metformin without an expanding (hydrogel) polymer.

This is not found persuasive because neither Cutie, the primary reference that teaches metformin in the core of the dosage form, nor Lewis teaches the requirement of an expanding (hydrogel) polymer. Therefore, the limitation of controlling the release of metformin without an expanding (hydrogel) polymer would have been obvious to one of ordinary skill in the art over the metformin core (without any expanding hydrogel polymer) taught by Cutie and Lewis.

Applicants argue that claims 44-46 are patentable over the references of record because none of the references of record either alone or combined disclose or suggest to a skilled artisan the use of a mixed solvent system to apply the immediate release pioglitazone layer. Applicants state that they have discovered that the mixed solvent

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system improves application, release and stability of the immediate release pioglitazone layer.

This is not persuasive because one of ordinary skill in the art would find the limitation of applying the pioglitazone coating by using a solvent mixture of water and an organic solvent obvious over the shell (comprising the pioglitazone) that is obtained by conventional microencapsulation process (Page 7, line 31 to Page 8, line 5). One of ordinary skill in the art would use a solvent or a mixture of solvents based on the desired encapsulation of pioglitazone and the recited mixture of water and an organic solvent would have been an obvious variant of the processes cited by Cutie.

Regarding Cutie, Applicants argue that there is no description of a controlled release metformin core, primary seal coating and immediate release pioglitazone coating as required by the pending claims and that the general description (Page 7, line 7 to Page 8, line 14) only provides a very broad suggestion of delayed release dosage forms. Applicants argue that this does not describe controlled release metformin dosage forms and, more importantly, controlled release metformin dosage forms wherein a semipermeable membrane controls the release of metformin.

This is not persuasive because the controlled release of metformin is obvious over the metformin core taught by Cutie (Page 1, lines 6-7 and Page 10, claim 8) and Lewis (Page 1, lines 30-35). Since the metformin is in the core and the core can be coated with controlled release polymers, one of ordinary skill in the art would find that the controlled release of metformin from the dosage form is implicit.

Applicants argue that the general description in Cutie of delayed release dosage forms would lead a skilled artisan to coat both the metformin and pioglitazone with an

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acid resistant enteric coating, thereby delaying the release of both the metformin and pioglitazone from the dosage form.

This is not persuasive because Cutie teaches metformin in a core and since metformin (in the core) can be coated with controlled release polymers, one of ordinary skill in the art would find that the controlled release of metformin from the dosage form is implicit. Cutie also teaches pioglitazone in a layer over this core (Page 10, claim 8). Since Cutie does not teach controlled release of the pioglitazone from this outer layer, the immediate release of pioglitazone would have been obvious to one of ordinary skill in the art. Therefore, controlled release of metformin and immediate release of pioglitazone is obvious over the teaching of Cutie.

Applicants argue that the addition of Lewis does not overcome the deficiencies of Cutie. Applicants argue that there is no mention, disclosure or suggestion of preparing a controlled release metformin core and an immediate release pioglitazone layer as required by the pending claims. Applicants argue that at best, the addition of Lewis merely leads a skilled artisan to insert an inert barrier between the metformin core and first pioglitazone layer of Cutie followed by the application of an enteric coating to the three layer structure.

This is not persuasive because Lewis is used as a supporting reference that provides the teaching that an inert barrier between the metformin core and first pioglitazone layer of Cutie can be formed. Lewis can be properly combined with Cutie because both references disclose metformin in the core of the dosage form and apply a thiazolidinedione in the outer layer of the metformin core.

Applicants argue that the addition of Vergez to Cutie and/or Lewis also would not lead a skilled artisan to the presently claimed invention. Applicants argue that the dual controlled release dosage form of Vergez is entirely different from the presently claimed invention. Applicants argue that the addition of Vergez to Cutie and/or Lewis would not lead the skilled artisan to the present invention but rather to metformin/pioglitazone dosage forms that release both drugs in a controlled or delayed manner.

This is not persuasive because Vergez is used as a supporting reference that provides the teaching of a semi permeable membrane as applied in an osmotic controlled release device. Vergez can be properly combined with Lewis and Cutie because the semi permeable membrane of Vergez allows controlled release of an active agent. One of ordinary skill in the art would use the semi permeable membrane of Vergez with the controlled release metformin core of Cutie in order to further control the release of metformin from the dosage form. One of ordinary skill in the art would have a reasonable expectation of success in producing a functional dosage form with controlled release of metformin from the core and immediate release of pioglitazone from the outer layer/coating.

Therefore the rejection of 09/29/08 is applied to new claims 35-46.

Provisional rejection of claims 1, 2, 4 and 8-10 under obviousness type double patenting

8. In light of Applicants' cancellation of claims 1-34 the rejection of claims 1, 2, 4 and 8-10 on the ground of nonstatutory obviousness-type double patenting over claims 1, 20, 33 and 37-38 of copending Application No. 11/094,493 (the '493 application) is rendered moot.

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9. However, Applicants' arguments, with respect to the new claims 35, 36, 38, and 40-42 have been fully considered but are not persuasive.

Applicants believe it is premature to submit a terminal disclaimer at the present time. Applicants state that they will consider submitting a terminal disclaimer if allowable subject matter is found in the present application and pending Application No.

11/094,493.

Until such time that a terminal disclaimer is filed and approved, this rejection will be applied to new claims 35, 36, 38, and 40-42.

Claim Objections

10. Claim 35 is objected to because of the following informalities: there is a typographical error on the second to last line of the claim. "... pioglitazone is release from the dosage ..." should recite: "... pioglitazone is released from the dosage ..."

11. Appropriate correction is required.

Claim Rejections - 35 USC § 103

12. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

13. Claims 35-46 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cutie et al. (WO 01/82875), in view of Lewis (WO 01/35940) and further in view of Vergez et al. (US 2006/0204578).

The claimed invention is a once a day oral pharmaceutical dosage form consisting essentially of:

- (a) a controlled release metformin core consisting essentially of:
 - (i) a mixture of metformin or a pharmaceutically acceptable salt thereof and at least one pharmaceutically acceptable excipient;
 - (ii) optionally a secondary seal coat surrounding the metformin mixture and
 - (iii) a semipermeable membrane surrounding the metformin mixture or the secondary seal coat if present;
- (b) a primary seal coat that does not contain an active pharmaceutical ingredient, that rapidly disperses or dissolves in water and that is applied to the semipermeable membrane of the controlled release core; and
- (c) an immediate release pioglitazone coating applied to the primary seal coat comprising:
 - (i) pioglitazone or a pharmaceutically acceptable salt thereof; and
 - (ii) a binder.

The dosage form exhibits the following metformin dissolution profile when tested in a USP Type 2 apparatus at 75 rpms in 900 ml of simulated intestinal fluid and 37°C: 10-45% of the metformin is released after four hours; 30-90% of metformin is released after eight hours. The dosage form exhibits the following pioglitazone dissolution profile when tested in a USP apparatus Type 1 apparatus at 100 rpm in a pH 2.0 HCl-0.3M KCl buffer solution: at least 79% of the pioglitazone is released after 20 minutes and at least 95% of the pioglitazone is released from the dosage form after 30 minutes.

Cutie teaches a "core formulation comprising a first layer comprising pioglitazone, which covers at least a portion of a core comprising the biguanide,

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metformin (i.e. glucophage)" (Page 1, lines 6-7). A core of the metformin is formed and a layer of pioglitazone hydrochloride is deposited on the core (Page 10, claim 8). This reference teaches that "the first layer should comprise pioglitazone hydrochloride because its dose requirement is lower compared to metformin. Additionally, it is slightly non-polar, its solubility rate slower, and its absorption rate thus dependent on its dissolution rate in the contents of the gastrointestinal tract compared with metformin" (Page 2, lines 26-30). The "core formulation ... is preferably fabricated by compression into a tablet" (Page 6, lines 15-16). The core formulation may be coated with sugar, shellac or other enteric coating agents (Page 7, lines 9-11). Cutie teaches that the core formulation can have an outer shell made of a biodegradable material (including cellulosic polymers, polyvinyl acetate, and polyvinyl alcohol) (Page 7, lines 13-28).

Cutie does not expressly teach a primary seal coat that does not contain an active pharmaceutical ingredient, that rapidly disperses or dissolves in water and that is applied to the controlled release core.

Lewis teaches a pharmaceutical composition comprising a thiazolidinedione that is formulated as a thin layer upon the surface of the metformin hydrochloride (Page 1, lines 30-35). The metformin hydrochloride is in a compacted form, such as a tablet and the composition also comprises an inert barrier layer between the layer containing thiazolidinedione and the metformin hydrochloride (Page 1, lines 36-39).

Cutie and Lewis do not expressly teach a semipermeable membrane.

Vergez teaches a controlled release osmotic device of two or more different active agents where the "core is surrounded by a membrane having at least one or two preformed holes. The first pharmaceutical composition provides a controlled release of

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a first active agent through its respective first preformed passageway(s) in the semipermeable membrane. The second pharmaceutical composition provides a controlled release of a second active agent through a respective second passageway(s) in the semipermeable membrane. Both layers deliver their respective active agent through osmotic pumping” (Page 2, [0015]). Semipermeable membrane materials including cellulose acetates, flux enhancing agents (PEG 400), and plasticizers are disclosed (Page 10, [0109]).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to make a core of the metformin and deposit a layer of pioglitazone hydrochloride on the core, as taught by Cutie, combine it with a composition comprising an inert barrier layer between a layer containing thiazolidinedione and metformin hydrochloride, as taught by Lewis, further combine it with the osmotic controlled release device comprising a semi permeable membrane, as taught by Vergez, and produce the instant invention.

One of ordinary skill in the art would have been motivated to do this because the inert barrier layer taught by Lewis protects the inner core comprising metformin hydrochloride, thereby enhancing the controlled release properties of the metformin hydrochloride and osmotic devices with semipermeable membrane components (such as cellulose polymers, flux enhancing agents and plasticizers) are known in the art, as evidenced by the osmotic controlled release device of Vergez.

Regarding instant claim 35, the limitation of “once a day oral” dosage form denotes a future-intended use and thus, does not accord patentable weight to the claims. The limitation of the controlled release metformin core would have been obvious

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over the core of metformin taught by Cutie (Page 1, lines 6-7 and Page 10, claim 8) and Lewis (Page 1, lines 30-35). The limitation of the primary seal coat that does not contain an active pharmaceutical ingredient would have been obvious over the coating of the core with sugar, shellac or other enteric coating agents as taught by Cutie (Page 7, lines 9-11), in view of the inert barrier layer between the layer containing thiazolidinedione and the metformin hydrochloride, as taught by Lewis (Page 1, lines 36-39). The limitation of the immediate release pioglitazone coat would have been obvious over the layer of pioglitazone hydrochloride on the core of metformin as taught by Cutie (Page 10, claim 8), in view of the thiazolidinedione that is formulated as a thin layer upon the surface of the metformin hydrochloride core as taught by Lewis (Page 1, lines 30-35). The limitation of the dissolution profile of the dosage form would have been obvious over the dosage form disclosed by Cutie that includes pioglitazone hydrochloride from 1mg to 45mg and metformin from 100mg to 2550mg (Page 3, lines 7-9). One with ordinary skill in the art would use the standard dissolution procedures from the USP to test the in vitro dissolution profile of the formulation of a core of metformin with a layer of pioglitazone hydrochloride. Since the metformin is in the controlled release core and the pioglitazone is in the immediate release portion of the dosage form (as taught by Cutie), long term release of the metformin (even after 8 hours) and short term or immediate release of the pioglitazone (after 30 minutes) would be obvious to one of ordinary skill in the art. The semipermeable membrane would have been obvious over the semipermeable membrane taught by Vergez (Page 10, [0109]). The limitation of the release of pioglitazone as tested in a USP apparatus would have been obvious over the dosage form disclosed by Cutie that includes pioglitazone hydrochloride from 1mg to

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45mg and metformin from 100mg to 2550mg (Page 3, lines 7-9). One with ordinary skill in the art would use standard dissolution procedures from the USP to test the in vitro dissolution profile of the formulation of a core of metformin with a layer of pioglitazone hydrochloride. Since the pioglitazone is in the immediate release portion of the dosage form (as taught by Cutie), short term or immediate release of the pioglitazone (after 20 minutes and after 30 minutes) would have been obvious to one of ordinary skill in the art.

Regarding instant claim 36, the limitation of the controlled release core as an osmotic tablet would have been obvious over the controlled release core of metformin that may contain "binders such as microcrystalline cellulose, gum tragacanth or gelatin; an excipient such as starch or lactose, a disintegrating agent such as alginic acid, Primogel®, corn starch ... a lubricant such as magnesium stearate ..." as taught by Cutie (Page 6, line 33 to Page 7, line 3). One with ordinary skill in the art would know that osmotic tablets are generally used for controlled or sustained release of active ingredients. One with ordinary skill in the art would know that osmotic tablets contain components such as binders and disintegrating agents that promote the gradual break down of the tablet that subsequently allows for controlled or sustained release.

Regarding instant claims 37 and 45, the limitation of 50-98% of metformin in the core would have been obvious over the 500mg of metformin HCl in the core (calculated percent: $500\text{mg}/520\text{mg} = 96.15\%$ of granules) as taught by Lewis (Page 7, lines 10-13). The limitation of 0.1-40% of a binding agent would have been obvious over the 15mg of polyvinylpyrrolidone (calculated percent: $15\text{mg}/520\text{mg} = 2.88\%$ of granules) as taught by Lewis (Page 7, Example 1, line 14). The limitation of 0-5% of a lubricant would have

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been obvious over the 5mg of magnesium stearate (calculated percent: $5\text{mg}/520\text{mg} = 0.96\%$) as taught by Lewis (Page 7, Example 1, line 15). The secondary seal coat surrounding the coat would have been obvious over the inert barrier layer between the layer containing thiazolidinedione and the metformin hydrochloride, as taught by Lewis (Page 1, lines 36-39). The semipermeable membrane would have been obvious over the semipermeable membrane taught by Vergez (Page 10, [0109]). The limitation of 50-99% of a polymer would have been obvious over the cellulose acetate (calculated percent: $19.05\text{mg}/20\text{mg} = 95.25\%$), polyethylene glycol 400 (calculated percent: $0.95\text{mg}/20\text{mg} = 4.75\%$) as taught by Vergez (Page 17, Example 1, Table - Coating A). The limitation of at least one passageway would have been obvious over the passageway in the semipermeable membrane as taught by Vergez (Page 2, [0015]).

Regarding instant claim 38, the limitation of the metformin hydrochloride would have been obvious over the metformin taught by Cutie (Page 2, lines 5-9) and the metformin hydrochloride taught by Lewis (Page 1, lines 24-25). The limitation of the pioglitazone hydrochloride would have been obvious over the pioglitazone hydrochloride taught by Cutie (Page 2, lines 10-13).

Regarding instant claim 39, the limitation of the release of metformin that is not regulated by an expanding polymer would have been obvious over the core comprising metformin which does not contain an expanding polymer, as taught by Cutie (Page 10, claim 8).

Regarding instant claim 40, the limitation of the T_{max} of metformin would have been obvious over the dosage form disclosed by Cutie that includes metformin from 100mg to 2550mg (Page 3, lines 7-9). One with ordinary skill in the art would administer

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the dosage form and measure the peak plasma levels of metformin. Controlled release is generally known to delay the release of an active ingredient. Since the metformin is sequestered in the controlled release core, it would have been obvious that the T_{max} would range from 8-12 hours.

Regarding instant claims 41 and 42, the limitation of the T_{max} of the pioglitazone would have been obvious over the dosage form disclosed by Cutie that includes pioglitazone hydrochloride from 1mg to 45mg (Page 3, lines 7-9). One with ordinary skill in the art would administer the dosage form and measure the peak plasma levels of the thiazolidinedione. Immediate release is generally known to hasten the release of an active ingredient. Since the pioglitazone is present in the immediate release layer, it would have been obvious that the T_{max} would range from 1-12 hours.

Regarding instant claims 43, 44 and 46, the limitation of the immediate release thiazolidinedione coat comprising pioglitazone would have been obvious over the coating with compound (I), as taught by Lewis (Page 7, lines 29-32) in view of the pioglitazone in a layer surrounding a core of metformin, as taught by Cutie (Page 10, claim 8), and further in view of the semipermeable membrane with at least one passageway, as taught by Vergez (Page 2, [0015]). Cutie teaches binders such as microcrystalline cellulose, gum tragacanth or gelatin (Page 6, line 33 to Page 7, line 1). Vergez teaches that soaps and detergents may be used as surfactants (Page 13, [0136]). The pore former would have been obvious over the PVP taught by Lewis (Page 7, Example 1, line 14). The use of water would have been obvious over the water used in the coating by Lewis (Page 7, line 32). One of ordinary skill in the art would find the limitation of applying the pioglitazone coating by using a solvent mixture of water and an

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organic solvent obvious over the shell (comprising the pioglitazone) that is obtained by conventional microencapsulation process (Page 7, line 31 to Page 8, line 5). One of ordinary skill in the art would use a solvent or a mixture of solvents based on the desired encapsulation of pioglitazone and the recited mixture of water and an organic solvent would have been an obvious variant of the processes cited by Cutie.

Double Patenting

14. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

15. Claims 35, 36, 38, and 40-42 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 20, 33 and 37-38 of copending Application No. 11/094,493 ('493 hereinafter). Although the conflicting claims are not identical, they are not patentably distinct from each other because both applications describe a controlled release core comprising metformin and an immediate release thiazolidinedione derivative containing component comprising

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pioglitazone. The difference is that instant claims are drawn to an immediate release thiazolidinedione containing coating and claims of '493 are drawn to an immediate release thiazolidinedione containing "component". It would have been obvious to one of ordinary skill in the art at the time the invention was made to prepare an immediate release component in the form of an immediate release coating with a thiazolidinedione. The same ranges for peak plasma levels (Tmax) of the pioglitazone are recited in instant claims and in claims of '493.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

13. No claims are allowed.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Aradhana Sasan whose telephone number is (571) 272-9022. The examiner can normally be reached Monday to Thursday from 6:30 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, can be reached at 571-272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Aradhana Sasan/
Examiner, Art Unit 1615

/MP WOODWARD/
Supervisory Patent Examiner, Art Unit 1615